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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,623	01/13/2004	Eckhart Bauer	1/1250-1-C1	2511

28501 7590 06/01/2006

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EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,623	BAUER ET AL.	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-7 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10226710.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 3-5 (in part), are drawn to a method of treating a disease or condition chosen from cancer, infections, inflammatory and autoimmune diseases comprising administering a therapeutically effective amount of compound of the formula (I), wherein R^3, R^4, R^5 and R^6 are identical or different and selected from among hydrogen, C_1-C_{10}-alkyl, C_2-C_{10}-alkenyl, C_2-C_{10}-alkynyl, aryl, C_3-C_8-cycloalkyl, -X-aryl, -X-cycloalkyl, NR^8-aryl, and -NR^8-cycloalkyl, or wherein R^3 and R^4, R^3 and R^5, or R^4 and R^5 together denote a 2-5-membered alkyl bridge, classified in class 514, several subclasses such as 886, 914, 888, 895, 898, 257, 275, and 253.02-253.04, class 544, several subclasses such as 253, and 380-392.

II. Claims 1 and 3-5 (in part), are drawn to a method of treating a disease or condition chosen from cancer, infections, inflammatory and autoimmune diseases comprising administering a therapeutically effective amount of compound of the formula (I), wherein R^3, R^4, R^5, and R^6 are identical or different and selected from among heteroaryl, C_3-C_8-heterocycloalkyl, -X-heteroaryl, -X-heterocycloalkyl, and -NR^8-heterocycloalkyl, or wherein R^3 and R^4, R^3 and R^5 or R^4 and R^5 denote a 2-5-membered alkyl bridge

containing 1 to 2 heteroatoms, classified in class 514, several subclasses such as 886, 914, 895, 898, and 253.02, class 544, several subclasses such as 233-234, 246-247, and 366-379.

III. Claims 2 and 3-5 (in part), are drawn to a method of treating a disease or condition chosen from HIV, Kaposi's sarcoma, colitis, arthritis, Alzheimer's disease, glomerulonephritis, conditions related to wound healing, bacterial, fungal and /or parasitic infections, leukaemias, lymphoma, solid tumours, psoriasis, bone diseases and cardiovascular disease comprising administering a compound of formula (I), wherein R^3, R^4, R^5 and R^6 are identical or different and selected from among hydrogen, C_1-C_{10}-alkyl, C_2-C_{10}-alkenyl, C_2-C_{10}-alkynyl, aryl, C_3-C_8-cycloalkyl, -X-aryl, -X-cycloalkyl, NR^8-aryl, and -NR^8-cycloalkyl, or wherein R^3 and R^4, R^3 and R^5, or R^4 and R^5 together denote a 2-5-membered alkyl bridge, classified in class 514, several subclasses such as 908, 888, 895, 898, , 257, 275, and 253.02-253.04, class 544, several subclasses such as 253, and 380-392.

IV. Claims 2 and 3-5 (in part), are drawn to a method of treating a disease or condition chosen from HIV, Kaposi's sarcoma, colitis, arthritis, Alzheimer's disease, glomerulonephritis, conditions related to wound healing, bacterial, fungal and /or parasitic infections, leukaemias, lymphoma, solid tumours, psoriasis, bone diseases and cardiovascular disease comprising

administering a compound of formula (I), wherein R^3, R^4, R^5 and R^6 are identical or different and selected from among heteroaryl, C_3-C_8-heterocycloalkyl, -X-heteroaryl, -X-heterocycloalkyl, and -NR^8-heterocycloalkyl, or wherein R^3 and R^4, R^3 and R^5 or R^4 and R^5 together denote a 2-5-membered alkyl bridge containing 1 to 2 heteroatoms, classified in class 514, several subclasses such as 908, 888, 895, 898, and 253.02, class 544 , several subclasses such as 233-234, 246-247, and 366-379.

V. Claim 6 (in part), is drawn to a method of treating a disease or condition chosen from cancer, infections, inflammatory and autoimmune diseases comprising administering a therapeutically effective amount of compound of the formula (II), wherein R^3, R^4, and R^5 are identical or different and selected from among hydrogen, C_1-C_{10}-alkyl, C_2-C_{10}-alkenyl, C_2-C_{10}-alkynyl, aryl, C_3-C_8-cycloalkyl, -X-aryl, -X-cycloalkyl, NR^8-aryl, and -NR^8-cycloalkyl, or wherein R^3 and R^4, R^3 and R^5, or R^4 and R^5 denote together denote a 2-5-membered alkyl bridge , classified in class 514, several subclasses such as 886, 914, 888, 895, 898, 253, and 380-392, class 544, several subclasses such as 241, 334, 257, and 275.

VI. Claim 6 (in part), is drawn to a method of treating a disease or condition chosen from cancer, infections, inflammatory and autoimmune diseases

comprising administering a therapeutically effective amount of compound of the formula (II), wherein R^3, R^4, and R^5 are identical or different and selected from among heteroaryl, C_3-C_8-heterocycloalkyl, -X-heteroaryl, -X-heterocycloalkyl, and -NR^8-heterocycloalkyl, or wherein R^3 and R^4, R^3 and R^5 or R^4 and R^5 denote a 2-5-membered alkyl bridge containing 1 to 2 heteroatoms, classified in class 514, several subclasses such as 886, 914, 895, 898, and 253.02, class 544, several subclasses such as 241, 334, 233-234, and 246-247.

VII. Claim 7 (in part), is drawn to a method of treating a disease or condition chosen from HIV, Kaposi's sarcoma, colitis, arthritis, Alzheimer's disease, glomerulonephritis, conditions related to wound healing, bacterial, fungal and /or parasitic infections, leukaemias, lymphoma, solid tumours, psoriasis, bone diseases and cardiovascular disease comprising administering a compound of formula (I), wherein R^3, R^4, and R^5 are identical or different and selected from among hydrogen, C_1-C_{10}-alkyl, C_2-C_{10}-alkenyl, C_2-C_{10}-alkynyl, aryl, C_3-C_8-cycloalkyl, -X-aryl, -X-cycloalkyl, NR^8-aryl, and -NR^8-cycloalkyl, or whereing R^3 and R^4, R^3 and R^5, or together denote a 2-5-membered alkyl bridge, classified in class 514, several subclasses such as 886, 914, 895, 898, 253, and 380-392, class 544, several subclasses such as 241, 334, 257, and 275.

VIII. Claim 7 (in part), is drawn to a method of treating a disease or condition chosen from HIV, Kaposi's sarcoma, colitis, arthritis, Alzheimer's disease, glomerulonephritis, conditions related to wound healing, bacterial, fungal and /or parasitic infections, leukaemias, lymphoma, solid tumours, psoriasis, bone diseases and cardiovascular disease comprising administering a compound of formula (II), wherein R^3, R^4, and R^5 are identical or different and selected from among heteroaryl, C_3-C_8-heterocycloalkyl, -X-heteroaryl, -X-heterocycloalkyl, and -NR^8-heterocycloalkyl, or wherein R^3 and R^4, R^3 and R^5 or R^4 and R^5 together denote a 2-5-membered alkyl bridge containing 1 to 2 heteroatoms, classified in class 514, several subclasses such as 886, 914, 895, 898, , and 253.02, class 544, several subclasses such as 241, 334, 233-234, and 246-247.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to various unrelated methods administering distinct compounds. In particular, Groups I, II, V, and VI are directed to a method of treating a disease or condition chosen from cancer, infections, inflammatory and autoimmune diseases comprising the administration of distinct

chemical compounds, whereas Groups III, IV, VII, and VIII are directed to a method of treating a disease or condition chosen from HIV, Kaposi's sarcoma, colitis, arthritis, Alzheimer's disease, glomerulonephritis, conditions related to wound healing, bacterial, fungal and /or parasitic infections, leukaemias, lymphoma, solid tumours, psoriasis, bone diseases and cardiovascular disease comprising administration of distinct chemical compounds. The method of Groups I, II, V, and VI are unrelated to all of the method of Groups III, IV, VII, and VIII. In particular, the treatment of wound healing in Groups III, IV, VII, and VIII is broad and can be associated with any type of disorder, disease or injury, whereas the treatment of cancer in Groups I, II, V, and VI is specifically associated with the proliferation of cells. Therefore, the treatment of Groups I, II, V, and VI and Groups III, IV, VII, and VIII I-IV are mediated at different sites of action and therefore have different modes of action, which can result in different drugs and hence different responses to the drug.

Additionally, the methods of treatment are drawn to the administration of unrelated and distinct chemical compounds. The differences in structural features will inherently result in different reactivity, solubility, oral bioavailability, etc. Thus, by virtue of the different structures and reactivity of Groups I-VIII, these unrelated inventions are distinct.

Because these inventions are distinct for the reasons given above and the individual search required for Groups I-VIII, restriction for examination purposes as indicated is proper. For instance, a search for a method of treating HIV would not render a proper and overlapping search for pain associated with breast cancer.

Likewise, a search for 2,3-diamino-7-(furan-3-yl)-7,8-dihydro-8-(pyridine-4-yl)-7-(thiazol-5-yl)pteridin-6(5H)-one (compound of formula I wherein $R^1 = NH_2$, $R^2 = H$, R^3 = furan, R^4 = thiazole, R^5 = pyridine, and R^6 and R^7 are hydrogen) would not render a proper and overlapping search for 2,4-diamino-7-cyclopentyl-7,8-dihydro-7,8-diphenylpteridin-6(5H)-one (compound of formula I wherein $R^1 = NH_2$, $R^2 = H$, R^3 = cyclopentane, R^4 = phenyl, R^5 = phenyl, and R^6 and R^7 are hydrogen). For this reason, Groups I-VIII are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups I-VIII have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Specie Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

1. A treatment, disclosed in all claims
2. A specific compound of formula (I), disclosed in claims 1-5
3. A specific compound of formula (II) disclosed in claims 6-7

Each above listed species are distinct because they encompass various unrelated disorders or conditions and diverse and unrelated structural moieties that a reference anticipating one of the species would not anticipate or render obvious of other species. Thus, the stated species are capable of supporting separate patents. Further, each recited species can be classified in different classifications. For example, a method of treating inflammation is classified in class 514, subclass 886 and 914, for example. However, a method treating arthritis is classified in class 514, subclass 825, leukemia is classified in class 514, subclass 908, and infections is classified in class 514, subclass 888, 895, and 898. The compounds of formula (I) wherein R^3, R^4, R^5 and R^6 are identical or different and selected from among hydrogen, C_1-C_{10}-alkyl, C_2-C_{10}-alkenyl, C_2-C_{10}-alkynyl, aryl, C_3-C_8-cycloalkyl, -X-aryl, -X-cycloalkyl, NR^8-aryl, and -NR^8-cycloalkyl, or wherein R^3 and R^4, R^3 and R^5, or R^4 and R^5 together denote a 2-5-membered alkyl bridge, classified in class 544, several subclasses such as 253, and 380-392. However, the compounds of formula (I) wherein R^3, R^4, R^5, and R^6 are identical or different and selected from among heteroaryl, C_3-C_8-heterocycloalkyl, -X-heteroaryl, -X-heterocycloalkyl, and -NR^8-heterocycloalkyl, or wherein R^3 and R^4, R^3 and R^5 or R^4 and R^5 denote a 2-5-membered alkyl bridge containing 1 to 2 heteroatoms, classified in class 514, subclass 253.02, class 544, several subclasses such as 233-234, 246-247, and 366-379. Additionally, the compounds of formula (II) wherein R^3, R^4, and R^5 are identical or different and selected from among heteroaryl, C_3-C_8-heterocycloalkyl, -X-heteroaryl, -X-heterocycloalkyl, and -NR^8-heterocycloalkyl, or wherein R^3 and R^4, R^3 and R^5 or R^4 and R^5 denote a 2-5-membered alkyl bridge

containing 1 to 2 heteroatoms, classified in class 544, subclasses 241 and 334, for example. Different classification of species is *prima facia* evidence of undue burden of search.

Accordingly, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant's election should thus identify the group elected and a specie from the various diseases, and a specific compound of formula (I) and (II), and any additional component that applicant construes relevant to the elected invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.141).

Because the above specie election requirement is complex, a telephone call to the applicant's agent to request an oral election was not made. See M.P.E.P. Sec 812.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER